

INDIAN HEALTH ADDENDUM TO MEDICARE PART D PLAN AGREEMENT

1. Purpose and Supercession of this Indian Health Addendum

The purpose of this Indian Health Addendum is to apply special terms and conditions to the Pharmacy Agreement between the _____ ("the Provider") and _____ (herein "Part D Plan Sponsor") for administration of the Medicare Prescription Drug Benefit program at pharmacies and dispensaries of the IHS as authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Pharmacy Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.

2. Definitions.

For purposes of the Pharmacy Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 422 and 42 CFR Part 423, as meeting the requirements and standards that apply to entities that offer prescription drug plans.

(b) The terms "Part D Plan" means a prescription drug coverage that is offered under a policy, contract or plan that has been approved as specified in 42 CFR 422.502 or 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the requirements under subpart K of 42 CFR 422 or subpart K of Part 423.

(c) The term "Indian Health Service" (IHS) means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661, and all pharmacies and dispensaries operated by the IHS.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "the Provider" means the Indian Health Service (IHS), and all pharmacies and dispensaries operated by the IHS.

(f) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(g) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "Dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum are the IHS operated Service Units, including hospitals, health centers and one or more pharmacies or dispensaries. Where IHS service units operate more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

4. Deductibles

The cost of pharmaceuticals provided at a pharmacy or dispensary of the Provider, or paid for by the Provider through a referral to a non-IHS retail pharmacy, shall count toward the deductible applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of the Provider.

(a) The parties agree that IHS is limited to serving eligible IHS beneficiaries pursuant to Part 136 of Title 42, Code of Federal Regulations and section 813(a) of the Indian Health Care Improvement Act, [IHCIA] 25 USC §1680c (a). The Provider may provide services to non-eligible persons only under certain circumstances in section 813(b) and in emergencies under section 813(c) of the IHCIA.

(b) No clause, term or condition of the Pharmacy Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to the IHS:

- (1) The Anti-Deficiency Act 31 U.S.C. § 1341;
- (2) The Indian Self Determination and Education Assistance Act (ISDEAA); 25 USC § 450 *et seq.*;

- (3) The Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671-2680;
- (4) The Federal Medical Care Recovery Act, 42 U.S.C. § 2651-2653;
- (5) The Federal Privacy Act of 1974, 5 U.S.C. § 552a, 42 C.F.R. Part 2;
- (6) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Parts 160 and 164.; and
- (7) The Indian Health Care Improvement Act (IHCIA), 25 U.S.C. § 1601 *et seq.*

7. Insurance and indemnification.

FTCA coverage available to IHS obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of IHS and their employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of IHS and their employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Pharmacy Agreement shall be interpreted to authorize or obligate any IHS employee to operate outside the scope of his/her employment. The IHS shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless.

8. Employee license.

States may not regulate the qualifications of Federal employees who are carrying out their authorized Federal activities within the scope of their employment. Consequently, the parties acknowledge that IHS employees are not subject to state licensure laws and IHS pharmacy departments are not licensed by individual states. The parties agree that during the term of the Pharmacy Agreement, IHS pharmacists are currently licensed in accordance with federal statutes and regulations, and the IHS facility is accredited in accordance with federal statutes and regulations. During the term of the Pharmacy Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

9. Dispute Resolution.

In the event of any dispute arising under the Participating Pharmacy Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Pharmacy Agreement.

10. Governing Law.

The Pharmacy Agreement and all addenda thereto shall be governed and

construed in accordance with Federal law of the United States. In the event of a conflict between the Pharmacy Agreement and all addenda thereto and Federal law, Federal law shall prevail.

11. Pharmacy/Dispensary Participation.

The Pharmacy Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider. Where pharmacies are required to use National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement, dispensaries will be use NCPDP Alternate Site Enumeration Program (ASEP) numbering for reimbursement.

12. Acquisition of Pharmaceuticals.

Nothing in the Pharmacy Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including medications purchased at Federal Supply Schedule and the HRSA 340B pricing. Nor shall anything in the Pharmacy Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

13. Point of Sale Processing.

Where the Part D Plan Sponsor's standard pharmacy agreement contains provisions related to drug utilization review and/or generic equivalent substitution and the Provider does not have the reasonable information technology capacity to comply with such, then the provisions shall not apply to the Provider. As specified in §423.132(c)(3) of the final rule, the notification of price differentials is waived for the Provider.

14. Submission of Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, the Provider shall submit a confirmation paper claim.

15. Payment Rate.

Claims from the Provider shall be paid at rates that are reasonable and appropriate.

16. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan to the Provider in paper and electronic format at no cost to the Provider.

17. Hours of Service.

The hours of service of the pharmacies or dispensaries of the Provider shall be established by the Provider. At the request of the Part D Plan, the Provider shall provide written notification of its hours of service to the Part D Plan.

18. Ethics language

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.